PATENT COOPERATION TREATY

7-21-99

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: PETER J. BUTCH, III
SYNNESTVEDT & LECHNER LLP
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1101 MARKET STREET
PHILADELPHIA PA 19107-2950

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing (day/month/year)	21 MAY 1999
Applicant's or agent's file reference: P22,590 PCT	REPLY DUE within TWO months from the above date of mailing

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/US98/18816	10 SEPTEMBER 1998	10 SEPTEMBER 1997

International Patent Classification (IPC) or both national classification and IPC
IPC(6): C08G 63/00, 63/02, 67/00, 69/00 and US Cl.: 528/176, 193, 271, 272

Applicant
RUTGERS, THE STATE UNIVERSITY

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I [X] Basis of the opinion
- II [ ] Priority
- III [ ] Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV [ ] Lack of unity of invention
- V [X] Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI [ ] Certain documents cited
- VII [ ] Certain defects in the international application
- VIII [ ] Certain observations on the international application

Rutgers
FOR FILE P22590 PCT
MAY 24 1999
SYNNESTVEDT & LECHNER
ATTEN: PJB/JRS

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 10 JANUARY 2000

Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	TERRESSA MOSLEY
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0651

Form PCT/IPEA/408 (cover sheet) (January 1994)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/18816

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :C08G 63/00, 63/02, 67/00, 69/00
US CL : 528/176, 193, 271, 272
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 528/176, 193, 271, 272

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,264,540 A (COOPER ET AL.) 23 November 1993 (23-11-93), abstract, column 5 lines 5-55, column 6 lines 5-55	1-40
X	US 4,997,904 A (DOMB) 05 March 1991 (05-03-91), abstract, column 2 Lines 5-55, column 4 Line 5-30.	1-40

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
14 DECEMBER 1998

Date of mailing of the international search report
14 JAN 1999

Name and mailing address of the ISA/US
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TERRESSA MOSLEY
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Form PCT/ISA/210 (second sheet)(July 1992)*

WRITTEN OPINION

International application No
PCT-US98/18816

I. Basis of the opinion

1. This opinion has been drawn on the basis of (*Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

[X] the international application as originally filed.

[X] the description, pages 1-18 , as originally filed.
pages NONE , filed with the demand.
pages NONE , filed with the letter of _____.

[X] the claims, Nos. 1-40 , as originally filed.
Nos. NONE , as amended under Article 19.
Nos. NONE , filed with the demand.
Nos. NONE , filed with the letter of _____.

[X] the drawings, sheets/fig NONE , as originally filed.
sheets/fig NONE , filed with the demand.
sheets/fig NONE , filed with the letter of _____

2. The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/fig NONE

3. [ ] This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:
NONE

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International application No.
PCT/US98/18816

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 STATEMENT

Novelty (N)	Claims	NONE	YES
	Claims	1-40	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-40	NO
Industrial Applicability (IA)	Claims	1-40	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-40 lack novelty under PCT Article 33(2) as being anticipated by USP 5,264,540, Kevin Cooper et al.

Cooper et al. discloses an improved process for preparing an aromatic polyanhydride is disclosed. The aromatic polyanhydride is prepared by reacting an aromatic dicarboxylic acid with an anhydride to form an anhydride prepolymer,isolating and purifying the prepolymer, and subjecting the prepolymer to melt polycondensation conditions. The improvement specifically relates to the purification of the acid so it is essentially free of impurities before it is reacted with the anhydride. The polymers prepared from the improved process have higher molecular weights than the molecular weights achieved from the prior art processes, and exhibit outstanding thermal stability and mechanical properties. This combination of properties allows the aromatic polyanhydrides to be melt processed to prepare numerous devices. In addition, these aromatic polyanhydrides are bioabsorbable, and this attribute in combination with its ability for melt processing makes the polyanhydrides particularly well-suited for the preparation of implantable surgical devices such as wound closure devices which are designed to absorb in the body when exposed to moist bodily tissue. Note applicants' "comprising" is open language and does not exclude those additional moieties etc. disclosed herein. In view of the above, there appears to be no significant difference between the reference and that which is claimed by applicant(s).Any differences not specifically mentioned appear to be conventional. Consequently, the claimed invention cannot be deemed as novel and accordingly is unpatentable.

Claims 1-40 lack novelty under PCT Article 33(2) as being anticipated by USP 4,997,904 Abraham J. Domb et al.

Domb discloses an aromatic anhydride copolymers containing at least two aromatic diacid units, which are soluble in chloroform or dichloromethane to concentrations between approximately 0.5 to 50% weight/volume, melt at temperatures below 180.degree. C., and have low crystallinity are disclosed. The copolymers may contain (Continued on Supplemental Sheet.)

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII Sheet 10

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

between 0 and approximately 30% aliphatic diacid units. All copolymers are insoluble in carbon tetrachloride, i.e., less than 0.1% polymer by weight/volume solvent). The desired properties are the result of adding between 10 and 90% of a second aromatic diacid, to the copolymer composition which introduces irregularity in the polymer chains that dramatically alter the polymer properties, decreasing the crystallinity and melting point and increasing the solubility in the common solvents, dichloromethane or chloroform. An additional decrease in Tg and MP, with an increase in flexibility, is obtained by adding small amount of aliphatic diacid, up to about 30%. Note applicants' "comprising" is open language and does not exclude those additional moieties etc. disclosed herein. In view of the above, there appears to be no significant difference between the reference and that which is claimed by applicant(s). Any differences not specifically mentioned appear to be conventional. Consequently, the claimed invention cannot be deemed as novel and accordingly is unpatentable.

Claims 1-40 lack an inventive step under PCT Article 33(3) as being obvious over USP 5,264,540, Kevin Cooper,et al.

Cooper et al. discloses an improved process for preparing an aromatic polyanhydride is disclosed. The aromatic polyanhydride is prepared by reacting an aromatic dicarboxylic acid with an anhydride to form an anhydride prepolymer,isolating and purifying the prepolymer, and subjecting the prepolymer to melt polycondensation conditions. The improvement specifically relates to the purification of the acid so it is essentially free of impurities before it is reacted with the anhydride. The polymers prepared from the unproved process have higher molecular weights than the molecular weights achieved from the prior art processes, and exhibit outstanding thermal stability and mechanical properties. This combination of properties allows the aromatic polyanhydrides to be melt processed to prepare numerous devices. In addition, these aromatic polyanhydrides are bioabsorbable, and this attribute in combination with its ability for melt processing makes the polyanhydrides particularly well-suited for the preparation of inplantable surgical devices such as wound closure devices which are designed to absorb in the body when exposed to moist bodily tissue.

Thus, the reference disclose the claimed invention except for the particular amounts and parameters as claimed . It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the particular amounts and/or parameters as claimed , since it is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality.

Claims 1-40 lack an inventive step under PCT Article 33(3) as being obvious over USP 4,997,904 Abrahan J. Domb,et al.

Domb,et al. discloses an aromatic anhydride copolymers containing at least two aromatic diacid units, which are soluble in chloroform or dichloromethane to concentrations between approximately 0.5 to 50% weight/volume, melt at temperatures below 180.degree. C., and have low crystallinity are disclosed. The copolymers may contain between 0 and approximately 30% aliphatic diacid units. All copolymers are insoluble in carbon tetrachloride, i.e., less than 0.1% polymer by weight/volume solvent). The desired properties are the result of adding between 10 and 90% of a second aromatic diacid, to the copolymer composition which introduces irregularity in the polymer chains that dramatically alter the polymer properties, decreasing the crystallinity and melting point and increasing the solubility in the common solvents, dichloromethane or chloroform. An additional decrease in Tg and MP, with an increase in flexibility, is obtained by adding small amount of aliphatic diacid, up to about 30%.

Thus, the reference disclose the claimed invention except for the particular amounts and parameters as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the particular amounts and/or parameters as claimed , since it is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. .

Claims 1-40 meet the criteria set out in PCT Article 33(4),since the claimed invention has industial applicability as a therapeutic treatment of digestive inflammation when administered orally.

NEW CITATIONS

NONE